



Attorney's Docket No.: 06275-034001 / D 1371-1 US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kjell Bäckström et al.
Serial No. : 08/601,005
Filed : March 1, 1996
Title : AEROSOL DRUG FORMULATIONS

Art Unit : 1619
Examiner : F. Choi

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Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO-1449, copies of which are enclosed.

This statement is being filed after a first Office action on the merits, but before receipt of a final Office action or a Notice of Allowance. A check for \$180 in payment of the late submission fee of \$1.17(p) is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

Dec. 1, 2002

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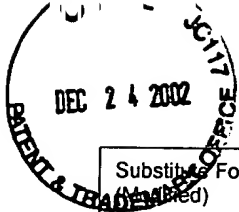
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Elissa Ferguson

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Elissa Ferguson

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(Rev. 11-95)U.S. Department of Commerce
Patent and Trademark OfficeAttorney's Docket No.
06275-034001Application No.
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**Information Disclosure Statement
by Applicant**

(Use several sheets if necessary)

(37 CFR §1.98(b))

Applicant
Kjell Bäckström et al.Filing Date
March 1, 1996Group Art Unit
1619

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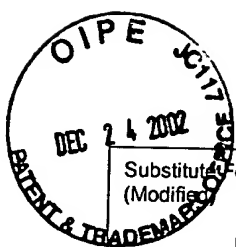
U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2,992,645	07/1961	Fowler			
	AB	3,671,625	06/1972	Altounyan			
	AC	4,462,983	07/1984	Azria			
	AD	4,524,769	06/1985	Wetterlin			
	AE	4,534,345	06/1985	Wetterlin			
	AF	4,537,772	08/1985	Alexander			
	AG	4,668,218	05/1987	Virtanen			
	AH	4,731,360	03/1988	Alexander			
	AI	4,907,583	03/1990	Wetterlin et al.			
	AJ	4,926,852	05/1990	Zoltan et al.			
	AK	5,122,127	06/1992	Stanley			
	AL	5,192,548	03/1993	Velasquez et al.			
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	AN	5,260,306	11/1993	Boardman et al.			
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	AP	5,320,094	06/1994	Laube et al.			
	AQ	5,341,800	08/1994	Clark et al.			
	AR	5,349,947	09/1994	Newhouse et al.			
	AS	5,352,461	10/1994	Feldstein et al.			
	AT	5,376,359	12/1994	Johnson			
	AU	5,376,386	12/1994	Ganderton et al.			
	AV	5,384,133	01/1995	Boyes et al.			
	AW	5,419,315	05/1995	Rubsamen			
	AX	5,437,271	08/1995	Hodson et al.			
	AY	5,451,569	09/1995	Wong et al.			
	AZ	5,458,135	10/1995	Patton et al.			
	AAA	5,474,759	12/1995	Fassberg et al.			

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U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	ABB	5,482,032	01/1996	Smith et al.			
	ACC	5,482,706	01/1996	Igari et al.			
	ADD	5,506,203 C1	02/2001	Bäckström et al.			
	AEE	5,518,998 C1	02/2001	Bäckström et al.			
	AFF	5,658,878	08/1997	Bäckström et al.			
	AGG	5,707,644	01/1998	Illum			
	AHH	5,747,445	05/1998	Bäckström et al.			
	AII	5,830,853	11/1998	Bäckström et al.			
	AJJ	5,858,968	01/1999	Weiner et al.			
	AKK	5,952,008	09/1999	Bäckström et al.			
	ALL	5,997,848	12/1999	Patton et al.			
	AMM	6,051,256	04/2000	Platz et al.			
	ANN	6,306,440	10/2001	Bäckström et al.			
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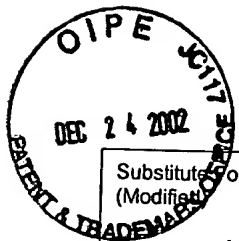
Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	APP	43 556/93	01/1994	Australia				
	AQQ	EP 0 023 359 A2	07/1980	European Patent Office				
	ARR	0 122 036	10/1984	European Patent Office				
	ASS	0 128 831	12/1984	European Patent Office				
	ATT	0 312 052 A1	10/1987	European Patent Office				
	AUU	0 364 235 A1	04/1988	European Patent Office				
	AVV	0 272 097	06/1988	European Patent Office				
	AWW	0 360 340 A1	03/1990	European Patent Office				
	AXX	0 455 463	11/1991	European Patent Office				
	AYY	0 383 751	09/1994	European Patent Office				

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Patent and Trademark OfficeAttorney's Docket No.
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(37 CFR §1.98(b))

Applicant
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March 1, 1996Group Art Unit
1619**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AZZ	JP 632 932	01/1988	Japan				
	AAAA	JP 1 117 825	05/1989	Japan				
	ABBB	JP 4 041 421	02/1992	Japan				
	ACCC	JP 4 149 126	05/1992	Japan				
	ADDD	8 807 820	11/1986	Sweden				
	AEEE	1 242 211	08/1971	United Kingdom				
	AFFF	1 520 247	08/1978	United Kingdom				
	AGGG	1 569 611	06/1980	United Kingdom				
	AHHH	WO 87/05213 A1	09/1987	WIPO				
	AIII	WO 90/04962	05/1990	WIPO				
	AJJJ	WO 91/16882	11/1991	WIPO				
	AKKK	WO 91/16929	11/1991	WIPO				
	ALLL	WO 91/18091 A1	11/1991	WIPO				
	AMMM	WO 92/04069	03/1992	WIPO				
	ANNN	WO 92/06704	04/1992	WIPO				
	AOOO	WO 93/25198	12/1993	WIPO				
	APPP	WO 94/22461	10/1994	WIPO				
	AQQQ	WO 95/00151	01/1995	WIPO				
	ARRR	WO 95/00128	01/1995	WIPO				
	ASSS	WO 96/19206	06/1996	WIPO				
	ATTT	WO 96/19207	06/1996	WIPO				
	AUUU							

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Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AVVV	Almer et al. "Insulin Inhalation - At Last A Breakthrough," <i>Diabetes Res. And Clin. Pract.</i> , 5:s163 (1988).

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Sheet 4 of 6

Substitute Form PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark OfficeAttorney's Docket No.
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Other Documents (include Author, Title, Date, and Place of Publication)

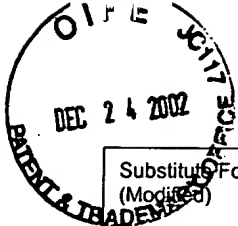
Examiner Initial	Desig. ID	Document
	AWWW	Aungst and Rogers, "Comparison of the Effects of Various Transmucosal Absorption Promoters on Buccal Insulin Delivery," <i>Int. J. Pharm.</i> (Netherlands), 53/3, 227-235 (1989).
	AXXX	Björk et al., "Characterization of degradable starch..." <i>International Journal of Pharmaceutics</i> , 62 (1990) 187-192.
	AYYY	Brange et al., "Monomeric Insulins and Their Experimental and Clinical Implications," <i>Diabetes Care</i> , 13:923-954 (1990).
	AZZZ	Byron et al., "Drug Delivery via the Respiratory..." <i>Journal of Aerosol Medicine</i> , 7:49-75 (1994).
	AAAAA	Chien et al., "Intranasal Drug Delivery for Systemic Medications," <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> , 4:67-194 (1987).
	ABBBB	Chien et al., "Potential Developments in Systemic Delivery of Insulin," <i>Drug Development and Industrial Pharmacy</i> , 15(10), 1601-1634 (1989).
	ACCCC	Colthorpe et al., "The Pharmacokinetics of Pulmonary-Delivered Insulin: A Comparison of Intratracheal..." <i>Pharmaceutical Research</i> , Vol. 9, No. 6, pp. 764-769 (1992).
	ADDDD	Dahlbäck et al., "Deposition of Tracer Aerosols in the Rabbit Respiratory Tract," <i>Journal of Aerosol Science</i> , Vol. 18, No. 6, pp. 733-736 (1987).
	AEEEE	Dahlbäck et al., "Regional Administration of Drugs to the Rabbit Respiratory Tract. Effects on Absorption," <i>Journal of Aerosol Medicine</i> , 1:222-223 (1988).
	AFFFF	Dempster et al., Anabolic Actions of Parathyroid Hormone on Bone, <i>Endocrine Reviews</i> 14: 690-709, (1993).
	AGGGG	"Diabetes Mellitus", Ch. VI in <i>Scientific American Medicine</i> , Scientific American, Inc., Apr. 1993.
	AHHHH	The Diabetes Control and Complications Trial Research Group, "The Effect of Intensive Treatment of Diabetes on the Development... Complications in Insulin-Dependent Diabetes Mellitus," <i>New England Journal of Medicine</i> , 329:977-986 (1993).
	AIIII	Elliott et al., "Parenteral absorption of insulin..." <i>Austr. Paediatr. J.</i> , 23:293-297 (1987).
	AJJJJ	Eppstein and Longenecker, "Alternative Delivery Systems for Peptides and Proteins As Drugs," <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> , 5:99-139 (1988).
	AKKKK	Goni et al., "Palmitoylcarnitine, a surface-active metabolite," <i>FEBS Lett.</i> , Vol. 390, pp. 1-5 (1996).
	ALLLL	Hoover et al., "Peptides are Better Absorbed from the Lung than the Gut in the Rat," <i>Pharmaceutical Research</i> , Vol. 9, No. 8, pp. 1103-1106 (1992).
	AMMMM	Jacobs, Maarten A.J.M., "The Pharmacodynamics and Activity of Intranasally Administered Insulin in Healthy Male Volunteers," <i>Diabetes</i> , Vol. 42, pp. 1649-1655 (1993).
	ANNNN	Jaegfeldt, H. et al., "Particle size distribution from different modifications of Turbuhaler®," Proceedings of an international workshop on a new inhaler, May 21-22, 1987 (London) pp. 90-99.
	AOOOO	Jones, "Pulmonary absorption of insulin", (1998) Ph.D. Thesis, Welsh School of Pharmacy, University of Wales, United Kingdom.
	APPPP	Köhler, Dieter, "Aerosols for Systemic Treatment," <i>Lung</i> , Supplement: 677-684 (1990).
	AQQQQ	Köhler et al., "Nicht radioaktives Verfahren zur Messung der Lungenpermeabilität: Inhalation von Insulin," <i>Aten-w-Lungenkrkh</i> , Jahrgang 13, Nr. Jun. 1987; 230-232.
	ARRRR	Lasker, "The Diabetes Control and Complications Trial," <i>The New England Journal of Medicine</i> , 329:1035-1036 (1993).

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Substitute Disclosure Form (PTO-1449)



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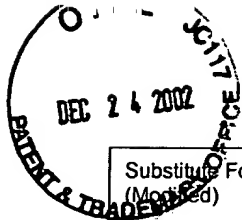
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-034001	Application No. 08/601,005
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Kjell Bäckström et al.	
		Filing Date March 1, 1996	Group Art Unit 1619

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	ASSSS	Laube et al., "Preliminary Study of the Efficacy of Insulin Aerosol Delivery by Oral Inhalation in Diabetic Patients," <i>Journal of the American Medical Association</i> , 239:2106-2109 (1993).
	ATTTT	Lecluyse et al., "In Vitro Effects of Long-Chain Acylcarnitines on the Permeability, Transepithelial Electrical Resistance and Morphology of Rat Colonic Mucosa," <i>J. Pharmacol. Exp. Ther.</i> , Vol. 265(2), pp. 955-62 (1993).
	AUUUU	Lee et al., "Development of an aerosol dosage form containing insulin," <i>Journal of Pharmaceutical Sciences</i> , Vol. 65, No. 4, pp. 567-574 (1976).
	AVVVV	Li, Yuping et al., "Effect of a Conjugated Bile Salt on the Pulmonary Absorption of Insulin in Rats," <i>Eur. J. Pharm. Biopharm.</i> , Vol. 39, pp. 216-221 (1993).
	AWWWW	Liu et al., "Pulmonary Delivery of Free...", <i>Pharmaceutical Research</i> , 10:228-232 (1993).
	AXXXX	Longenecker et al., "Effects of Sodium Taurodihydrofusidate on Nasal Absorption of Insulin in Sheep," <i>J. Pharm. Sci.</i> , 76(5): 351-355 (1987).
	AYYYY	Mizgala et al., "Renal Handling of Phosphate," <i>Physiological Reviews</i> , 65(2): 431-466 (1985).
	AZZZZ	Nagai et al., "Powder Dosage Form of Insulin for Nasal Administration," <i>J. Controlled Release</i> , 1:15-22 (1984).
	AAAAAA	Nagano et al., "New Method of Insulin...", <i>Jikeikai Medical Journal</i> , 32: 503-506 (1985).
	ABBBBB	Newman, "Chapter 9: Therapeutic aerosols", In: <i>Aerosols and the Lung: Clinical and Experimental Aspects</i> , (1984) Butterworth & Co., United Kingdom.
	ACCCCC	O'Hagan and Illum, "Absorption of Peptides and Proteins from the Respiratory Tract and the Potential for Development of Locally Administered Vaccine," <i>Critical Reviews in Therapeutic Drug Carrier Sys</i> , 7:35-97 (1990).
	ADDDDD	Okumura et al., "Intratracheal delivery of insulin absorption from solution and aerosol by rat lung," <i>International Journal of Pharmaceutics</i> , Vol. 88, pp. 63-73 (1992).
	AEEEEEE	Olanoff et al., "Method to Enhance Intranasal Peptide Delivery," in "Controlled-Release Technology Pharmaceutical Applications", Lee et al, American Chemical Society, 301-309 (1987).
	AFFFFFF	Patton et al., "Bioavailability of Pulmonary Delivered Peptides and Proteins: α -interferon, Calcitonins and Parathyroid Hormones," <i>Journal of Controlled Release</i> , 28: 79-85 (1994).
	AGGGGG	Patton et al., "(D) Routes of Delivery: Case Studies," <i>Advanced Drug Delivery Reviews</i> , Vol 8, pp. 179-196 (1992).
	AHHHHH	Reeve et al., Anabolic Effect of Human Parathyroid Hormone Fragment on Trabecular Bone in Involutional Osteoporosis: A Multicentre Trial, <i>British Medical Journal</i> , pp. 1340-1344, (1980).
	AIIIII	<i>Remington's Pharmaceutical Science</i> , 18 th edition., p. 1079 (1990).
	AJJJJJ	Ruin, "Diabetics May Not Need Their Insulin Shots," article in <i>Sydsvenska (Dagbladet)</i> , Monday, Jun. 12, 1989.
	AKKKKK	Sakr., "A new approach for insulin...", <i>International Journal of Pharmaceutics</i> , 86:1-7 (1992).
	ALLLLL	Salzman et al., "Intranasal Aerosolized Insulin Mixed-Meal Studies and Long-term Use in Type 1 Diabetes," <i>The New England Journal of Medicine</i> , 1312:1078-1084 (1985).
	AMMMMM	Schanker et al., "Species Comparison of Drug Absorption from the Lung Aerosol Inhalation or Intratracheal Injection," <i>Drug Metabolism & Disposition</i> , Vol. 14, pp. 79-88 (1986).

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-034001	Application No. 08/601,005
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		Filing Date March 1, 1996	Group Art Unit 1619

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	ANNNNN	Schluter et al., "Pulmonary Administration... Type 1 Diabetics" Abstract #298, <i>Diabetes</i> , 33 (Supplement): 75A (1984).
	AOOOOC	Selam and Charles, "Devices for Insulin Administration," <i>Diabetes Care</i> , 13:955-979 (1990).
	APPPPP	Timsina et al., "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers," <i>Int. J. Pharmaceutics</i> , 101:1-13 (1994).
	AQQQQC	Wang et al., <i>Parenteral Science and Technology</i> , 42 (2S), S4-S26, 1988.
	ARRRRR	Wetterlin, Kiell, "Turbuhaler: A New Powder Inhaler for Administration of Drugs to the Airways," <i>Pharmaceutical Research</i> , Vol. 5, pp. 506-508, (1988).
	ASSSSS	Wigley et al., "Insulin Across Respiratory Mucosae by Aerosol Delivery," <i>Diabetes</i> , 20:552-556 (1971).
	ATTTTT	Yamamoto et al., "Absorption Enhancement of Intrapulmonary Administered Insulin by Various Absorption...", <i>J. Pharm. Pharmacol.</i> , Vol. 46, pp. 14-18 (1994).
	AUUUUU	Zingg et al., "Transhepatic Absorption and Biliary Excretion of Insulin," <i>Can. J. Physiol. Pharmacol.</i> , 65:1982-1987 (1987).
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